

APR 5 2005

K043527

510(k) Summary

General Information

Classification: Class I
Classification Name: Ear, Nose & Throat Manual Surgical Instrument
Regulation Code: 21 CFR 874.4420
Product Code: LRC
Trade Name: *Relieva* Sinus Balloon Dilation Catheter
Submitter: ExploraMed NC1, Inc.
2570 West El Camino Real, Suite 310
Mountain View, CA 94040
Telephone: (650) 472-0300
Contact: William M. Facteau
President & CEO
Date Revised: 05 April 2005

Intended Use

The *Relieva* Sinus Balloon Dilation Catheter is intended to provide a means to dilate ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

Device Description

The *Relieva* Sinus Balloon Dilation Catheter will be provided in the following balloon sizes:

- 3 mm Sinus Balloon Catheter
- 5 mm Sinus Balloon Catheter
- 7 mm Sinus Balloon Catheter

The family of *Relieva* Sinus Balloon Dilation Catheters allows for the enlargement of sinus ostia and paranasal spaces with a minimally invasive method. The *Relieva* Sinus Balloon Dilation Catheters are placed in the narrow opening over a guidewire. Once positioned the balloons are inflated with a high pressure inflation device that provides feedback as to the internal pressure of the balloon. After a few seconds at the desired balloon inflation pressure, the balloon can be deflated and removed or repositioned.

Materials

All materials used in the manufacture of the *Relieva* Sinus Balloon Catheter are suitable for their intended use and have been used in numerous previously cleared products.

Testing

Products were tested to ensure conformance to product specification.

Testing included:

- Visual Inspection
- Dimensional Analysis
- Surface Finish
- Catheter Hub Leak
- Shaft to Hub Separation
- Balloon Inflation Cycle Fatigue
- Balloon Burst Pressure

Summary of Substantial Equivalence

The *Relieva* Sinus Balloon Catheter is substantially equivalent to marketed predicate devices with respect to intended use and technological characteristics.

Comparison Chart of Relieva Sinus Balloon Catheter and Predicate Devices

	Relieva Sinus Balloon	Circular Cutting Punch	Antrum Curette	Lacricath
Manufacturer	ExploraMed NC1	Karl Storz Endoscopy America	Karl Storz Endoscopy America	Atrion
510(k) Number	K043527	Pre-Amendments	Pre-Amendments	K935233
CFR Section	874.4420	874.4420	874.4420	886.4350
Device Classification	I	I	I	I
Product Code	LRC	LRC	LRC	HNW
Intended Use	Dilation of tissue	Dilation of tissue	Dilation of tissue	Dilation of tissue
Working Diameter	3mm, 5mm, 7mm	4.5mm	5mm	3mm, 5mm
Working Length	30cm	18cm	19cm	20cm



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ExploraMed II, Inc.
c/o William M. Facteau
President & CEO
2570 W. El Camino Real
Suite 310
Mountain View, CA 94040

Re: K043527
Trade/Device Name: Relieva Sinus Balloon Catheter
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 24, 2005
Received: March 25, 2005

Dear Mr. Facteau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): This application

Device Name: *Relieva* Sinus Balloon Dilation Catheter

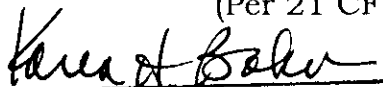
Indications for Use: The *Relieva* Sinus Balloon Dilation Catheter is intended to provide a means to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

PLEASE DO NOT WRITE BELOW THIS LINE –
(CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☐ OR
(Per 21 CFR 801.109)

Over-The-Counter Use
(Optional Format 1-2-96)



(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

ExploraMed NC1, Inc. Confidential Information

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